IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INDIVIOR INC. and INDIVIOR UK LIMITED, Plaintiffs, vs. ACTAVIS LABORATORIES UT, INC., Defendant.	C.A. No. 18-499-RGA

DEFENDANT'S AMENDED ANSWER,
AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendant Actavis Laboratories UT, Inc. ("Actavis"), by and through its undersigned attorneys, submits its amended answer to the complaint of plaintiffs Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) and Indivior UK Limited (formerly known as RB Pharmaceuticals Limited). Defendant denies all allegations in plaintiffs' complaint except as specifically admitted below. This pleading is based upon Actavis' knowledge of its own activities, and upon information and belief as to the activities of others.

NATURE OF THE ACTION

1. Defendant admits that it submitted an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture, use, and sell a generic version of Suboxone®, a sublingual film containing buprenorphine hydrochloride and naloxone hydrochloride, prior to the expiration of the patent-in-suit. Except as expressly admitted, defendant denies the remaining allegations contained in paragraph 1.

THE PARTIES

2. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2 and therefore denies them.

3. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 3 and therefore denies them.

4. Defendant admits that Actavis Laboratories UT, Inc. is a Delaware corporation having a place of business at 577 Chipeta Way, Salt Lake City, Utah 84108.

JURISDICTION AND VENUE

5. Defendant answers that it does not contest subject matter jurisdiction for purposes of this action only.

6. Defendant admits it is a pharmaceutical company engaged in the business of developing and manufacturing generic pharmaceutical products, some of which are ultimately distributed, marketed, and/or sold in Utah and throughout the United States. Except as expressly admitted, defendant denies the remaining allegations contained in paragraph 6.

7. Defendant answers that it does not contest personal jurisdiction over Actavis for purposes of this action only. Defendant admits that it maintains a place of business and is registered to do business in Utah. Except as expressly admitted, defendant denies the remaining allegations contained in paragraph 7.

8. Defendant answers that it does not contest that venue is proper in this District for purposes of this action only.

THE PATENT-IN-SUIT

9. Defendant admits that Indivior UK is identified on the face of the ’454 patent as the assignee. Defendant further admits that, on its face, the ’454 patent is titled “Sublingual and buccal film compositions,” and issued to inventors Garry L. Myers, Samuel D. Hilbert, Bill J. Boone, Beuford Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan by the United States Patent and Trademark Office on June 27, 2017. Defendant further admits that Exhibit A to the

complaint appears to be a copy of the '454 patent. Defendant avers that the allegation that the '454 patent was duly and legally issued states a legal conclusion to which no response is required, but if a response is required, defendant denies the same. Defendant lacks knowledge or information sufficient to form a belief about the remaining allegations contained in paragraph 9 and therefore denies them.

SUBOXONE® SUBLINGUAL FILM

10. Defendant admits that the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") entry for New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film lists "Indivior Inc." as the applicant. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in paragraph 10 and therefore denies them.

11. Defendant admits that the Orange Book entry for NDA No. 22-410 lists the FDA approval date as August 30, 2010. Defendant admits the labeling for Suboxone® sublingual film currently states that the product is "indicated for maintenance treatment of opioid dependence." Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in paragraph 11 and therefore denies them.

12. Defendant admits that the '454 patent is currently listed in the "Orange Book" with respect to Suboxone® sublingual film. Except as expressly admitted, defendant denies the remaining allegations contained in paragraph 12.

THE DRUG APPROVAL PROCESS

13. Defendant admits that in 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, which is commonly known as the "Hatch-Waxman Act" and which

is codified at 21 U.S.C. § 355. The remaining allegations contained in paragraph 13 are characterizations of the Hatch-Waxman Act, or conclusions of law, that do not require any response from defendant. To the extent that a response is required, defendant answers that the provisions of the Hatch-Waxman Act speak for themselves.

14. The allegations contained in paragraph 14 are characterizations of the Hatch-Waxman Act, or conclusions of law, that do not require any response from defendant. To the extent that a response is required, defendant answers that the provisions of the Hatch-Waxman Act speak for themselves.

15. The allegations contained in paragraph 15 are characterizations of the Hatch-Waxman Act, or conclusions of law, that do not require any response from defendant. To the extent that a response is required, defendant answers that the provisions of the Hatch-Waxman Act speak for themselves.

16. The allegations contained in paragraph 16 are characterizations of the Hatch-Waxman Act, or conclusions of law, that do not require any response from defendant. To the extent that a response is required, defendant answers that the provisions of the Hatch-Waxman Act speak for themselves.

17. The allegations contained in paragraph 17 are characterizations of the Hatch-Waxman Act, or conclusions of law, that do not require any response from defendant. To the extent that a response is required, defendant answers that the provisions of the Hatch-Waxman Act speak for themselves.

18. The allegations contained in paragraph 18 are characterizations of the Hatch-Waxman Act, or conclusions of law, that do not require any response from defendant. To the

extent that a response is required, defendant answers that the provisions of the Hatch-Waxman Act speak for themselves.

19. The allegations contained in paragraph 19 are characterizations of the Hatch-Waxman Act, or conclusions of law, that do not require any response from defendant. To the extent that a response is required, defendant answers that the provisions of the Hatch-Waxman Act speak for themselves.

ACTAVIS' PARAGRAPH IV NOTICE

20. Defendant admits that it sent notification letters regarding ANDA Nos. 204383 and 207087 to plaintiffs dated August 2, 2017, and August 24, 2017, providing information pursuant to the Hatch-Waxman Act.

21. Defendant admits that it sent notification letters regarding ANDA Nos. 204383 and 207087 to plaintiffs dated August 2, 2017, and August 24, 2017, providing information pursuant to the Hatch-Waxman Act. Defendant further admits that Actavis' generic ANDA products are bioequivalent to the Suboxone® sublingual film. Except as expressly admitted, defendant denies the remaining allegations contained in paragraph 21.

22. Admitted.

COUNT 1
Infringement of the '454 Patent Under 35 U.S.C. § 271(e)(2)

23. Denied.

24. Defendant admits that the filing of ANDA Nos. 204383 and 207087 is a technical act of infringement under 35 U.S.C. § 271(e)(2) that gives rise to subject matter jurisdiction. Defendant expressly denies that Actavis' proposed ANDA products infringe any valid claim of the '454 patent.

25. Denied.

PRAYER FOR RELIEF

The remainder of plaintiffs' complaint recites a prayer for relief to which no response is required. To the extent that a response is required, defendant denies that plaintiffs are entitled to any remedy or relief, including those requested.

AFFIRMATIVE DEFENSES

Without any admission as to the burden of proof, burden of persuasion, or the truth of any allegation in plaintiffs' complaint, defendant states the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE

The filing of Actavis' ANDA No. 204383 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '454 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE

The manufacture, use, sale, or offer for sale of Actavis' proposed generic product that is the subject of ANDA No. 204383 has not infringed, does not infringe, and would not—if marketed—infringe any valid and enforceable claim of the '454 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

THIRD AFFIRMATIVE DEFENSE

The filing of Actavis' ANDA No. 207087 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '454 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE

The manufacture, use, sale, or offer for sale of Actavis' proposed generic product that is the subject of ANDA No. 207087 has not infringed, does not infringe, and would not—if

marketed—infringe any valid and enforceable claim of the '454 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

FIFTH AFFIRMATIVE DEFENSE

The claims of the '454 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of sections 101, 102, 103, 111, 112, 116, 135, 256, and 287, and/or the doctrine of obviousness-type double patenting.

SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part by the doctrine of res judicata and/or collateral estoppel, including, but not limited to, the doctrines of issue preclusion and claim preclusion.

SEVENTH AFFIRMATIVE DEFENSE

The complaint fails to state a claim upon which relief can be granted.

EIGHTH AFFIRMATIVE DEFENSE

Actavis' actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

NINTH AFFIRMATIVE DEFENSE

Actavis has not willfully infringed any claim of the '454 patent.

TENTH AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

WHEREFORE, Actavis requests that plaintiffs' complaint be dismissed with prejudice and that Actavis be awarded the costs of this action, its attorneys' fees, and all other relief this Court deems just and proper.

COUNTERCLAIMS

For its counterclaims against plaintiffs/counterclaim defendants Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) and Indivior UK Limited (formerly known as RB Pharmaceuticals Limited), defendant/counterclaim plaintiff Actavis Laboratories UT, Inc. ("Actavis") alleges as follows:

THE PARTIES

1. Actavis Laboratories UT, Inc. is a Delaware corporation having a place of business at 577 Chipeta Way, Salt Lake City, UT 84108.

2. On information and belief, as stated in its complaint, plaintiff/counterclaim defendant Indivior Inc. is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

3. On information and belief, as stated in its complaint, plaintiff/counterclaim defendant Indivior UK is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

JURISDICTION AND VENUE

4. These counterclaims arise under the Patent Act, 35 U.S.C. §§ 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. To the extent this Court has subject matter jurisdiction over plaintiffs/counterclaim defendants' claims against Actavis, this Court has subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 2201 and 2202, as well as 35 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Indivior because, among other reasons, Indivior subjected itself to the jurisdiction of this Court by previously filing complaints against Actavis here. *See, e.g.*, C.A. Nos. 13-1674-RGA, 14-1574-RGA, and 18-497-RGA.

6. This Court has personal jurisdiction over Indivior because, among other reasons, Indivior UK Limited subjected itself to the jurisdiction of this Court by previously filing complaints against Actavis here. *See, e.g.*, C.A. Nos. 13-1674-RGA, 14-1574-RGA, and 18-497-RGA.

7. To the extent this venue is appropriate for plaintiffs/counterclaim defendants' claims against Actavis, venue is also appropriate in this Court for the following counterclaims. Venue is also proper in this judicial district under 28 U.S.C. § 1391(b) and (c).

8. There is an actual and justiciable controversy between the parties as to the infringement, validity, and enforceability of U.S. Patent No. 9,687,454.

BACKGROUND

9. Upon information and belief, as stated in plaintiffs/counterclaim defendants' complaint against Actavis, Indivior holds NDA No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

10. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or method of using such drug for which the NDA is submitted. The FDA lists these patents in the FDA publication entitled, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book").

11. Upon information and belief, plaintiffs/counterclaim defendants listed in the Orange Book certain patents that purportedly claim Suboxone® sublingual film and/or a method of using Suboxone® sublingual film.

THE PATENT-IN-SUIT

12. The '454 patent, entitled "Sublingual and Buccal Film Compositions," indicates on its face that it issued on June 27, 2017.

13. Upon information and belief, as stated in plaintiffs/counterclaim defendants' complaint against Actavis, Indivior UK is the owner of the '454 patent and Indivior Inc. is an exclusive licensee of the '454 patent.

RELATED LITIGATION BETWEEN THE PARTIES

14. Actavis submitted ANDA No. 204383 to obtain FDA approval to engage in the commercial manufacture, use, and sale of buprenorphine hydrochloride and naloxone hydrochloride sublingual films ("proposed ANDA products") before expiration of the Orange Book patents.

15. ANDA No. 204383 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) indicating that the claims of the '454 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the proposed ANDA products.

16. Actavis submitted ANDA No. 207087 to obtain FDA approval to engage in the commercial manufacture, use, and sale of the proposed ANDA products described therein before expiration of the '454 patent.

17. ANDA No. 207087 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) indicating that the claims of the '454 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the proposed ANDA products.

18. On April 3, 2018, Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.), Indivior UK Limited (formerly known as RB Pharmaceuticals Limited), and Aquestive Therapeutics (formerly known as MonoSol Rx LLC), filed a complaint in this Court

alleging that Actavis' submission of ANDA Nos. 204383 and 207387 to the FDA infringed claims of U.S. Patent No. 9,931,305. *See, e.g.*, C.A. No. 18-497-RGA, D.I. 1.

19. On April 30, 2018, Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.), Indivior UK Limited (formerly known as RB Pharmaceuticals Limited), and Aquestive Therapeutics (formerly known as MonoSol Rx LLC) filed an amended complaint in this Court alleging that Actavis' submission of ANDA Nos. 204383 and 207387 to the FDA infringed claims of U.S. Patent No. 9,855,221. *See, e.g.*, C.A. No. 18-497-RGA, D.I. 6.

COUNT I
(Declaratory Judgment of Noninfringement of the '454 Patent)

20. Actavis repeats and re-alleges the allegations in paragraphs 1-19 above as if fully set forth here.

21. The manufacture, use, sale, offer for sale and/or importation of the proposed ANDA products will not infringe, directly or indirectly, any valid or enforceable claim of the '454 patent.

22. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, or importation of the proposed ANDA products will infringe the '454 patent.

23. Actavis is entitled to a judicial declaration that it has not infringed, does not infringe, and will not infringe—literally or under the doctrine of equivalents, directly or indirectly, by inducement or contribution—any valid claim of the '454 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '454 Patent)

24. Actavis repeats and re-alleges the allegations in paragraphs 1-23 above as if fully set forth here.

25. The claims of the ’454 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation, one or more of sections 101, 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

26. There is an actual and justiciable controversy between the parties as to whether the ’454 patent claims are valid.

27. Actavis is entitled to a declaratory judgment that the claims of the ’454 patent are invalid.

28. This is an exceptional case, and Actavis is entitled to its costs and reasonable attorneys’ fees.

PRAYER FOR RELIEF

WHEREFORE, Actavis prays that the Court enter judgment in its favor and against plaintiffs/counterclaim defendants as follows:

a. Dismissing plaintiffs/counterclaim defendants’ complaint with prejudice and denying each request for relief made by plaintiffs/counterclaim defendants;

b. Declaring that the filing of ANDA No. 204383 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the ’454 patent;

c. Declaring that the filing of ANDA No. 207087 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the ’454 patent;

d. Declaring that the manufacture, use, sale, offer for sale, and/or importation in the United States of the proposed ANDA products that are the subject of ANDA

No. 204383 does not, and will not infringe any valid and enforceable claim of the '454 patent;

e. Declaring that the manufacture, use, sale, offer for sale, and/or importation in the United States of the proposed ANDA products that are the subject of ANDA No. 207087 does not, and will not infringe any valid and enforceable claim of the '454 patent;

f. Declaring that the claims of the '454 patent are invalid;

g. Awarding Actavis its costs and expenses in this action;

h. Awarding Actavis its attorneys' fees pursuant to 35 U.S.C. § 285; and

i. Awarding other and further relief as this Court deems just and proper.

DATED this Xth day of May, 2018.

Respectfully submitted,

/s/ *John C. Phillips, Jr.*

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